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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,108	10/19/2000	Louise Elizabeth Donnelly	7500-0010	7685

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/31/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/694,108	DONNELLY ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-30* is/are rejected.

7)☒ Claim(s) *19 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 6, 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-30 are presented for prosecution on the merits.

Information Disclosure Statement

Applicant's Information Disclosure Statements received Feb. 22, 2001, April 22, 2002 and May 13, 2002 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63© and 37 CFR 1.76.

Claim Objections

2. Claims 1, 21, 22, 27, 29 are objected to because of the following informalities: In claim 1, line 6, after "and analogs thereof", the "and" should be deleted and replaced with --or--. In claims 21 and 22, line 2, after "exposure" the "is" should be deleted. In claim 27, line 1, after "claim 26", the "wherein the" should be deleted. In claim 29, line 4, after "and analogs thereof", the "and" should be deleted and replaced with --or--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claim 30 is rejected under 35 U.S.C. 102(a) as being anticipated by DANNENBERG WO 00/13685.

DANNENBERG discloses lozenges containing resveratrol for treating sore throat (please see example IV, page 24). DANNENBERG additionally teaches methods for treating inflammatory diseases of the head and neck comprising administering compositions containing resveratrol. The compositions may comprise lozenge, rinses or oral sprays. Please see page 18, lines 21-22; page 19; claims 1 and 4.

5. Claim 30 is rejected under 35 U.S.C. 102(a) as being anticipated by GOODMAN 6,022,901.

GOODMAN discloses pharmaceutical compositions containing resveratrol, cis-resveratrol, trans-resveratrol, a pharmaceutically acceptable salt, ester, amide, prodrug, or analog thereof. w/d The compositions may be in a form suitable for nasal aerosol or inhalation. Please see the abstract; col. 7, line 66 to col. 8, line 7 and lines 25-27.

> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claim 29 is rejected under 35 U.S.C. 102(e) as being anticipated by PEZZUTO et al., 6,414,037.

PEZZUTO et al. disclose pharmaceutical compositions for treating humans or animals suffering from skin disorders, wherein the compositions comprise resveratrol, a pharmaceutically w/d acceptable salt, ester, amide, prodrug, or analog thereof and anti-inflammatory agents or antibiotics. Please see the abstract; col. 10, lines 16-19 and lines 45-50.

7. Claim 30 is rejected under 35 U.S.C. 102(e) as being anticipated by FISCHER et al., 6,329,422.

FISCHER et al. disclose pharmaceutical compositions for treating cystic fibrosis, chronic w/d bronchitis or asthma, the compositions comprising active agents such as resveratrol and

pharmaceutically acceptable aerosol propellants useful for endopulmonary and/or intranasal inhalation administration. Please see col. 6, lines 58-67; col. 11, lines 47-60; col. 13, lines 24-30; claim 28.

8. Claims 1, 11, 12, 13, 14, 15, 18, 24, 25 are rejected under 35 U.S.C. 102(e) as being anticipated by FISCHER et al., 6,329,422.

FISCHER et al. disclose methods for treating for treating cystic fibrosis, chronic bronchitis or asthma in a patient, wherein the methods comprise administering effective amounts of a composition containing flavones and resveratrol. The compositions contain pharmaceutically acceptable aerosol propellants useful for endopulmonary and/or intranasal inhalation administration or the compositions may be administered orally. Please see col. 6, lines 58-67; col. 11, lines 47-60; col. 12, lines 61-63; col. 13, lines 24-30; claim 28.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-10, 16, 17, 21-23, 26-28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over FISCHER et al., supra in view of GOLDBERG et al. (journal article), and PEZZUTO et al., supra and Goodman & Gilman's Ninth Edition and American Drug Index, Facts and Comparisons.

FISCHER et al. as applied above.

FISCHER et al. do not specifically disclose administration of the claimed analogs or cis- or trans-isomers of the resveratrol, nor does FISCHER et al. teach that resveratrol is an anti-inflammatory agent; however, the Examiner turns to (1) GOLDBERG which teaches that

resveratrol contained in plants has been used in Japan for the treatment of inflammatory disorders (please see page 159, second column, first paragraph); and (2) PEZZUTO et al., which discloses that salt, esters, prodrugs, amides or analogs of resveratrol as well as trans-resveratrol, cis-resveratrol, trans- or cis-resveratrol glucoside are biologically active compounds, i.e have pharmaceutical activity (please see the abstract; col. 1, lines 29-35) and further that resveratrol has antioxidant and anti-inflammatory properties (please see col. 3, lines 15-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of FISCHER et al. to include the trans or cis isomers of resveratrol because, in view of GOLDBERG and PEZZUTO's teachings, one of ordinary skill in the art would reasonably expect these isomers to be equally effective in treating cystic fibrosis, chronic bronchitis or asthma. Such a modification would have been motivated by the reasoned expectation of successfully treating patients suffering from cystic fibrosis, chronic bronchitis or asthma.

In addressing claim 29, FISCHER et al. do not disclose combining resveratrol with glucocorticoids; however, the Examiner refers to Goodman & Gilman's which discloses that glucocorticoids are know to be useful in treating asthma (please see page 666). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compositions of FISCHER to additionally include glucocorticoids because such a modification would have been motivated by the reasoned expectation that the combined effect of resveratrol and glucocorticoids would successfully treat the patients suffering from asthma.

Concerning claims 21-23, in view of GOLDBERG's and PEZZUTO's disclosure, one of ordinary skill in the art would reasonably expect resveratrol and its anti-inflammatory properties to treat inflammation resulting from occupational or environmental exposure to smoke, dust or allergens.

With respect to claims 16-17, FISCHER et al. do not specifically disclose treating atopic asthma, however, one of ordinary skill in the art would reasonably expect resveratrol which is capable of treating asthma to be equally effective in treating atopic or non-atopic asthma.

Finally, concerning claims 26-28, PEZZUTO et al. disclose pharmaceutical compositions containing resveratrol and anti-inflammatory agents or antibiotics (col. 10, lines 16-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of FISCHER et al. to include additional anti-inflammatory agents or antibiotics (as suggested by PEZZUTO) because one of ordinary skill in the art would reasonably expect the anti-inflammatory agents or antibiotics to treat or prevent any inflammation or infections that may result from or accompany the asthma, bronchitis or cystic fibrosis. Moreover, it would have been obvious to one of ordinary skill in the art to modify the methods of FISCHER et al. to additionally administer bronchodilators such as theophylline and salmetrol xinafoate, as taught by American Drug Index, or the use of antiasthmatics such as cromolyn sulfate and beta-adrenergic agonists, (as taught by Goodman & Gilman's, pages, 666, 667-668), because one of ordinary skill in the art would reasonably expect these bronchodilators and/or the antiasthmatics to be equally effective in treating the patients suffering from asthma. In

other words, one of ordinary skill in the art would reasonably expect that the combination of resveratrol and bronchodilators and/or antiasthmatics would successfully treating a subject suffering from asthma.

12. Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 1-18, 21-30 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

July 28, 2002.

Cybille Delacroix-Muirheid
Patent Examiner Group 1600